

REMARKS

Claims 1-30 were pending in the application. Claims 3, 13 and 18 have been cancelled, without prejudice, as being directed to a non-elected invention. Claims 5, 14, 22 and 30 have been cancelled to expedite prosecution. Applicants reserve the right to pursue these claims as originally filed in this or a separate application(s). Claims 1, 2, 4, 6-12, 15, 16, and 25 have been amended. Accordingly, after the amendments presented herein have been entered, claims 1-2, 4, 6-12, 15, 16, 17, 19-21, 23, 24, and 26-30 will remain pending.

The Examiner acknowledges Applicants' election without traverse of Group II, claims 1, 2, 4-12 and 14-30, in part, for continued examination. Accordingly, Applicants have amended the pending claims of Group II to specify only SEQ ID NO: 2, corresponding to Group II.

No new matter has been added. Any amendments to and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and were done solely to expedite the prosecution of the application.

Objection to Drawings

The Examiner has objected to Fig. 4A because it does not include the reference sign(s) mentioned in the description. The Examiner further objects to Figs. 4D and E as being too dark to discern the indicated complexes. As confirmed during the telephonic conversation between Applicants' attorney and the Examiner on October 28, 2003, Applicants will attend to filing replacement drawings before acceptance and payment of the issue fee.

Objection to Claims

The Examiner has objected to claims 1 and 16-30 for being drawn, in part, to non-elected subject matter. Claim 22 has been cancelled. Applicants have amended claims 1, 16-21 and 23-30 to correspond with the elected subject matter (SEQ ID NO: 2). Accordingly, the objection is now moot.

The Examiner has objected to claims 5-12 and 15 as being in improper multiple dependent claim form. Claim 5 has been cancelled. Applicants have amended claims 6-12 and 15 be in proper dependent form. Accordingly, the objection is now moot.

The Examiner has objected to claims 22 and 30 as being in improper dependent form for failing to further limit the subject matter of a previous claim. Claims 22 and 30 have been cancelled, thereby rendering the objection moot.

Rejection of Claims 1, 2, 4, 16-17 and 19-30 Under 35 U.S.C. § 112

The Examiner has rejected claims 1, 2, 4, 16-17 and 19-30 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that recitation of the phrase “regulatory element derived from the nucleotide sequence of SEQ ID NO: 2” is indefinite because “it is unclear whether applicant is claiming that any derivative of any length from SEQ ID NO: 2 would be encompassed by the claim(s).”

Applicants respectfully disagree. However, to expedite prosecution of the present application, claims 22 and 30 have been cancelled, and claims 1, 2, 4, 16-17, 19-21 and 23-29 have been amended to delete reference to the language objected to by the Examiner. In particular, the claims have been amended to specify that the isolated polynucleotide comprises or consists of SEQ ID NO:2. Therefore, the rejection of pending claims 1, 2, 4, 16-17, 19-21 and 23-29 for indefiniteness is now moot.

Rejection of Claims 1, 2, 4, and 16-30 Under 35 U.S.C. § 112

The Examiner has rejected claims 1, 2, 4, and 16-30 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of filing, had possession of the claimed invention. Specifically, the Examiner states that the disclosure fails to teach “the exact functional domains within SEQ ID NO: 2 that would be necessary to effect inducible transcription of operably-linked heterologous polynucleotides.” The Examiner further states that the claims “read on a genus of any regulatory elements derived from SEQ ID NO: 2 or

having at least about 70 percent sequence identity to SEQ ID NO: 2”, and “thus the claims as written encompass a multitude of species.”

Applicants respectfully disagree. However, to expedite prosecution of the present application, claims 22 and 30 have been cancelled, and claims 1, 2, 4, 16-17, 19-21 and 23-29 have been amended such that they no longer encompass a “genus of any regulatory elements derived from SEQ ID NO: 2” or a genus of regulatory elements which have “at least about 70 percent sequence identity to SEQ ID NO: 2,” as objected to by the Examiner. Claims 17, 19-21 and 23-24 depend from amended claim 16, and claims 26-29 depend from amended claim 25. In view of the claim amendments, the rejection of the pending claims for lack of written description is now moot. Accordingly, reconsideration and withdrawal of the rejection of claims 1, 2, 4, 16-17, 19-21 and 23-29 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejection of Claims 1, 2, 4, and 14 Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 2, 4 and 14 under 35 U.S.C. § 102(b) as being anticipated by Wan *et al.* (*DNA Cell Biology* 1994 13(11): 1127-36). The Examiner relies on Wan *et al.* for teaching “the exact same sequence of the human MnSOD gene (SEQ ID NO: 2)” and for characterizing “the 5’ regulatory region revealing that the region within 708 bp of the putative transcription initiation site contains no TATA box or CAAT box.” The Examiner further relies on Wan *et al.* for teaching that “the region includes multiple transcription binding sites within 400 bp of the initiation site, a stretch rich in GC, strongly suggesting the role of this region as a regulatory element.” The Examiner concludes that “since Wan *et al.* teaches the same sequence (SEQ ID NO:2), the biological activities associated with said sequence would be inherent.”

Claim 14 has been cancelled. Therefore, the rejection is moot as applied to this claim. Applicants respectfully traverse the rejection as applied to claims 1, 2 and 4.

As amended, claim 1 is directed to an isolated polynucleotide comprising a manganese superoxide dismutase (MnSOD) regulatory element *operably linked to a heterologous polynucleotide*, wherein the regulatory element comprises the nucleotide sequence of SEQ ID NO:2 and is capable of causing inducible transcription or expression of an operably linked heterologous polynucleotide. Wan *et al.* fails to teach an isolated polynucleotide comprising a MnSOD

regulatory element operably linked to a heterologous polynucleotide, as claimed. Indeed, Wan *et al.* merely teaches the nucleotide sequence of the complete manganese superoxide dismutase gene. Thus, the subject matter of claim 1 is not anticipated by the teachings of Wan *et al.*

As amended, claim 2 is directed to an isolated human manganese superoxide dismutase (MnSOD) regulatory element *consisting of* the nucleotide sequence of SEQ NO:2, the regulatory element being capable of causing inducible transcription or expression of an operably linked heterologous polynucleotide. Newly amended claim 4, which depends from claim 2, is directed to an isolated regulatory element of claim 2 *operably linked to a heterologous polynucleotide* so that, upon activation of the regulatory element, transcription or expression of the heterologous polynucleotide is induced.

Wan *et al.* fails to teach or suggest the subject matter of claims 2 or 4. As previously discussed, Wan *et al.* teaches the full-length genomic sequence of the human MnSOD gene. The authors do not teach or suggest an isolated regulatory element *consisting of* the nucleotide sequence of SEQ ID NO:2, as claimed. Nor do the authors teach or suggest a MnSOD regulatory enhancer element *operably linked to a heterologous polynucleotide*, as claimed. Accordingly, reconsideration and withdrawal of the rejection of claims 1, 2 and 4 under 35 U.S.C. § 102(b) is respectfully requested.

Applicants believe that no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. UFJ-002US from which the undersigned is authorized to draw.

Dated: January 28, 2004

Respectfully submitted,

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